DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
a14284

60 8th Street, N.E.
Atlanta, Georgia 30309

June 7, 2001

VIA FEDERAL EXPRESS

Bill K. Eckerd, President
W. K. Eckerd & Sons, Inc.
5067 Blythe Island Highway
Brunswick, GA 31520

Warning Letter
01-ATL-47

Dear Mr. Eckerd:

On May 10, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at Brunswick, Georgia. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh, histamine-susceptible fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for histamine fish, namely mahi mahi, tuna, amberjack, and wahoo, does not list the critical control point (CCP) of cooler storage for controlling the hazard of histamine formation.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine fish lists a critical limit at the Receiving CCP, i.e., *Received Product at Proper Temp*, that is not adequate to control the histamine hazard. In addition to establishing an adequate critical limit(s), you should review your plan's monitoring and record keeping procedures and make any appropriate changes if needed to ensure compliance with the critical limit(s).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to

include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District